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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,831	10/17/2005	Tetsuya Nakatsura	P26795	5642

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
08/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/525,831	NAKATSURA ET AL.	
	Examiner	Art Unit	
	ANNE L. HOLLERAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 27* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 5/5/2008 is acknowledged. Claims 1-20 and 22-26 were canceled. Claim 27 was added. Claims 21 and 27 are pending.

Newly submitted claim 27 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 21, drawn to a cancer vaccine comprising a DNA, or recombinant virus or recombinant bacteria comprising said DNA, and further comprising an adjuvant, wherein the DNA is a DNA encoding a cancer antigen comprising a protein having the amino acid sequence of SEQ ID NO: 1, or a protein having an amino acid sequence comprising a substitution, deletion, insertion, and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and also having immune-stimulating activity; or wherein the DNA is a) a DNA having the nucleotide sequence of SEQ ID NO: 2, b) a DNA having 90% or more homology to SEQ ID NO: 2, and encoding a protein having immune-stimulating activity, or a DNA having a partial sequence of the DNA of "a" or "b", and encoding a protein having immune stimulating activity.

Group II, claim(s) 27, drawn to a method of cancer vaccination, which comprises administering the cancer vaccine of claim 21.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the feature that is common to inventions groups I-II is that of a DNA encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 1. A DNA encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 is taught in the prior art by Old (WO 99/04265; published 28 January 1999; cited in the IDS; see page 683-685; see previous Office action). Therefore, a DNA encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 is not a special technical feature that makes a contribution over the prior art as a whole.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 27 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants' remarks concerning rejoinder after allowable subject matter is indicated are acknowledged.

In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim 21 is examined on the merits.

Claim Rejections/Objections Withdrawn:

Claim Objections

The objection to claim 9 is withdrawn in view of the cancellation of claim 9.

Claim Rejections - 35 USC § 112

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of claim 10.

The rejection of claim 10 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of claim 10.

The rejection of claims 9, 10, 21, 23,24 and 26 under 35 U.S.C. 102(b) as being anticipated by Scanlan (US 6,403,373; issued Jun. 11, 2002) is withdrawn in view of the cancellation of claims 9, 10, 23, 24 and 26, and for claim 21, because claim 21 now recites a cancer vaccine comprising an adjuvant.

The rejection of claims 9, 10, 21, 23, 24 and 26 under 35 U.S.C. 102(b) as being anticipated by Scanlan-II (Scanlan, M.J. et al., Int. J. Cancer 76: 652-658, 1998; cited in the IDS) is withdrawn in view of the cancellation of claims 9, 10, 23, 24 and 26, and for claim 21, because claim 21 now recites a cancer vaccine comprising an adjuvant.

The rejection of claims 9, 10, 21, 23, 24, and 26 under 35 U.S.C. 102(b) as being anticipated by Nakatsura (Biochemical and Biophysical Research Communications, 281: 936-944, 2001; cited in IDS) or Ishihara (Ishihara, K. et al. Biochem. Biophys. Acta, 1444: 138-142, 1999) is withdrawn in view of the cancellation of claims 9, 10, 23, 24 and 26, and for claim 21, because claim 21 now recites a cancer vaccine comprising an adjuvant.

The rejection of claims 9, 10, 21, 23, 24 and 26 under 35 U.S.C. 102(e) as being anticipated by Horne (US 6,974,667; issued 12/13/2005; effective filing date is Jun. 14, 2001),

Kaser (US 6,727,006; issued 4/27/2004; effective filing date is Jul. 30, 2001), or Cocks (US. 6,607,879; issued Au. 19, 2003; effective filing date is Feb. 9, 1998) is withdrawn in view of the cancellation of claims 9, 10, 23, 24 and 26, and for claim 21, because claim 21 now recites a cancer vaccine comprising an adjuvant.

Claim Rejections Maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 21 remains rejected under 35 U.S.C. 102(b) as being anticipated WO 99/04265 (Old, L. J. et al., published 28 January 1999; cited in IDS) as evidenced by Accession No. AAX40073 (12 July 1999, WO 99/04265-A2, Database N_Geneseq_200701).

Applicants' arguments have been carefully considered, but fail to persuade. Applicants state that WO 99/04265 discloses a nucleic acid expressed by colorectal cancer and normal cells, which falls into an extremely large group of disclosed nucleic acid sequences, referred to in the WO 99/04265 document as NA Group I, where this document refers to such molecules only as diagnostic agents or as antigens. Applicants' state that WO 99/04265 does not teach a cancer vaccine as claimed, nor do the documents teach the specific combination of recited elements such that they comprise a cancer vaccine. Applicants bring to the examiner's attention Ex parte Bobsein (Appeal NO. 2005-1332) and In re Arkley, 172 USPQ 524 (CCPA 1972).

In response, the examiner notes that WO 99/04265 also characterizes the nucleic acid sequence of SEQ ID NO: 582 as belonging to NA Group 12, a subset of NA Group 3 coding for a human colon cancer antigen, where NA Group 3 is a subset of NA Group I, which are specifically disclosed as nucleic acids that are comprised within pharmaceutical compositions (page 6, lines 5-6), and the pharmaceutical compositions may include adjuvants. Therefore, WO 99/04265 discloses a particular nucleic acid sequence within the scope of the nucleic acid sequences encompassed by claim 21, discloses specifically that that particular nucleic acid sequence may be comprised with a pharmaceutical composition and that that pharmaceutical composition may include an adjuvant. Therefore, WO 99/04265 provides all of the elements recited in the claim, which are a nucleic acid and an adjuvant. Contrary to applicants' assertion, no "picking and choosing", as referred to in *In re Arkley,* (The examiner has not considered *Ex*

parte Bobsein, as this was a decision not written for publication and is not binding precedent of the Board.) is required in order to put together the claimed composition of a cancer vaccine. Therefore, the rejection is maintained for the reasons of record.

New Grounds of Rejection:

The following rejection is necessitated by the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 21 is drawn in part to a DNA vaccine comprising a DNA having 90% or more homology to SEQ ID NO: 2, and encoding a protein having immune-stimulating activity. Applicants point to support in the originally filed claims and in various passages of the specification. In particular, pages 11 and 12. These passages teach DNA molecules that hybridize to SEQ ID NO: 2, where the hybridizing DNA has for example 90% homology with a probe. As discussed in the previous Office action, a similar 10 was found to lack support in the

specification because a hybridizing DNA encodes a protein that is very different from the one encoded by SEQ ID NO: 2 itself. Thus, the passages pointed to on pages 11 and 12 do not support a claim to a cancer vaccine comprising a DNA having 90% or more sequence homology to SEQ ID NO: 2, because the specification refers to 90% or more homology with respect to the sequence that hybridizes to SEQ ID NO: 2. Therefore, the amendment introduces new matter into the specification as originally filed.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
August 4, 2008

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643